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| 10/776,387 | 02/10/2004 | Scott V. Taylor | AUS-2265-AL | 3912 |

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| EXAMINER |
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KOTINI, PAVITRA

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| ART UNIT | PAPER NUMBER |
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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/776,387 | Applicant(s) TAYLOR ET AL. | |
| | Examiner Pavitra Kotini | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 6, 10, 11, 13, 14, 26-30, 32-46, 49-53, 56-63 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12, 15-25, 31, 47, 48, 54, 55 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election **without** traverse of Group I, Species 1 in the reply filed on 4/27/07 is acknowledged. Claims 6, 10, 11, 13, 14, 26-30, 32-36, 43-46, 49-53, 56-63, and 67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Furthermore, claims 37-42 which are drawn to figure 23, are also withdrawn because they are not directed to the elected species of figure 3, which does not contain voids. Therefore, claims 1-5, 7-9, 12, 15-25, 31, 47, 48, 54, 55, and 64-66 will be prosecuted on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 12, 15, 17, 18, 23, 41, 42, 64-66 are rejected under 35

U.S.C. 102(b) as being anticipated by Gentelia et al. (US-5201714).

Gentelia discloses a trocar adapted to provide access for a surgical instrument through a body wall and into a body cavity, comprising:

Regarding **claim 1**, a cannula (3) having a proximal end and a distal end; a seal housing (2) communicating with the cannula to define a working channel (14); a seal assembly (6-11) disposed within the seal housing (2); at least one roller (6 or 7) included in the seal assembly (6-11) and having an axle (10 or 11) supported by the seal housing; and the roller having properties for forming a zero seal in the absence of the instrument (fig. 4), and an instrument seal in the presence of the instrument (fig. 1).

Regarding **claim 2**, the roller (6 or 7) is pivotal with the axle (10 or 11) relative to the seal housing (2).

Regarding **claim 3**, the axle (10 or 11) has a fixed relationship with the seal housing (col.2, line 8); and the roller (6 or 7) has a pivotal relationship with the axle (fig.1).

Regarding **claim 4**, the roller in radial cross-section has the configuration of a geometric shape (fig. 1).

Regarding **claim 5**, the geometric shape is a circle (fig. 1).

Regarding **claim 7**, the roller is a first roller (6), the axle is a first axle (10), and the trocar further comprises: a second roller (7) disposed on a second axle (11) in sealing engagement with the first roller, the second axle having a general parallel relationship with the first axle (figs.1, 4).

Regarding **claim 12**, the roller is a first roller (6) rotatable on a first axis (10) and the trocar further comprises at least one second roller (7) rotatable on a second axis (11) different than the first axis (fig. 1).

Gentelia discloses a surgical combination, comprising:

Regarding **claim 15**, an instrument (5) having a diameter of at least about one millimeter; an access device (1) adapted to facilitate disposition of the instrument across a body wall; a cannula (3) included in the access device and having an axis extending between a proximal end and a distal end; a seal housing (2) communicating with the cannula, to define a working channel (14) with the cannula; a seal assembly (6-11) disposed within the seal housing (2) of the access device (1); a roller (6 or 7) included in the seal assembly, the roller being sized and configured to form a zero seal in the absence of the instrument (fig. 4) and an instrument seal in the presence of the instrument (fig. 1).

Regarding **claim 17**, the roller has an axle with two ends; at least one of the ends of the axle being supported by the housing (fig. 1; col.2, line 53).

Regarding **claim 18**, an interior wall disposed within the seal housing (13); and the roller having properties for forming the zero seal with the interior wall (fig. 4).

Regarding **claim 23**, it is old and well known for instruments palced inside the body wall to be formed of translucent materials. See US patent #s 6319266, 5236417, and 4670008.

Regarding **claim 41**, Gentelia discloses a trocar assembly, comprising: a cannula (3) having a proximal end and a distal end; a seal housing (2) having an inner surface (13) and being disposed at one of the proximal end and the distal end of the cannula; a roller (6 or 7) having a resilient outer surface and an axle (10 or 11) for pivoting the outer surface relative to the inner surface of the seal housing (figs. 1 and 4; col.2, lines 52-56) and portions of the inner surface of the seal housing defining at least one recess

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(angular grooves in which rollers sit against) configured and arranged to receive the axle (fig. 1 and 4).

Regarding **claim 42**, the axle has at least one end with an area in radial cross-section, the size of the recess being generally greater than the area of the axle end (fig. 1).

Regarding **claim 64**, Gentelia discloses a valve assembly adapted to receive an elongate object and to form an object seal with the object, the assembly comprising: a valve housing (21) having a first opening (25) at a first end and a second opening (24) at a second end; a valve (37) disposed in the valve housing and forming a housing seal with the valve housing (fig. 6); and the valve having properties for forming a first object seal when the object is inserted through the first opening at the first end of the valve assembly, and alternatively forming a second object seal when the object is inserted into the second opening at the second end of the valve housing (fig. 7).

Regarding **claim 65**, the valve housing has an axis extending through the first opening and the second opening (fig. 6); and the valve is symmetrical about the axis of the valve assembly (fig. 6).

Regarding **claim 66**, in the absence of an object, the valve has properties for forming a first zero seal (between rollers 31 and 32) to inhibit fluid flow through the first opening (25), and alternatively a second zero seal (valve 37) to inhibit fluid flow through a second opening (24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gentelia et al. (5201714)

Gentelia ('714) discloses the invention substantially as claimed above, wherein the first roller (6) has the configuration of a first cylinder with a first radius; the second roller (7) has the configuration of a second cylinder with a second radius (fig. 1), but fails to disclose the first axle is separated from the second axle a distance not greater than the sum of the first radius and the second radius.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the valve assembly disclosed by ('714) to have the location of the axles directly at the center of the roller, separated only by sum of the radius of the rollers, because Applicant has not disclosed in the instant specification that the axles separated only by the sum of the radius of the rollers provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Gentelia's valve assembly with axles offset to the side because the intended use of

forming a zero seal and a instrument seal is still possible with Gentelia's valve assembly.

Claims 9, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentelia et al. (5201714) in view of Gentelia et al. (5599348).

Gentelia patent ('714) discloses the invention substantially as claimed above and further discloses the roller (6 or 7) is sized and configured to form the instrument seal (fig. 1) with the instrument seals of zero diameter (fig. 4) and small and larger diameter (col.3, lines 21-35), but fails to specifically disclose the size of the instrument seal.

However, Gentelia patent ('348) teaches instrument seals of varying sizes and an upper limit in a range between about six millimeters and 12 millimeters, and the diameter of the instrument capable of being at least about 5 millimeters or 10 millimeters (col.4, lines 24-42). Therefore, it would have been obvious to a person of ordinary skill in the art to modify the valve seal assembly disclosed by ('714) to include instrument seals of particular sizes in the upper range of 6-12 millimeters, as taught by ('348). Such a modification would allow the trocar to accommodate different sized instruments.

Claims 16, 19, 20, 24, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentelia et al. (5201714) in view of Yoon (US-5429609).

Regarding claims 16,19, and 20 Gentelia discloses a roller supported on the axle and rotatable with the axle relative to the seal housing, wherein the axle has a fixed

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relationship with the seal housing (col.2, line 53). Regarding claims 24, Gentelia discloses a cannula (3) extending along an axis between a proximal end and a distal end; a seal housing (2) communicating with the cannula to define a working channel (14); a roller (6 or 7) disposed within the seal housing, the roller being pivotal on an axis (10 or 11); and the roller being moveable by the inserted instrument to pivot the resilient material relative to the axis to inhibit tearing of the resilient material (figs.1-4; col.1, lines 57-61). Regarding claim 24, the roller has an end surface (contact surface between the two rollers; fig. 4) and a circumferential surface (contact surface between rollers and inside surface 13); and an instrument (5) inserted into the working channel encounters a frictional resistance associated with the end surface (5 is frictionally in contact with end surface of rollers) and a rolling resistance associated with the circumferential surface (surface 13 against rollers provides a rotational resistance). Regarding claim 31, Gentelia discloses the roller is a first roller (6), the axis is a first axis (10), and the trocar assembly further comprises: a second roller (7) disposed within the seal housing (2) and being pivotal on a second axis (11) different than the first axis.

Gentelia fails to disclose the roller having a compliant material such as a gel material and a resilient material included in the roller and having properties susceptible to tearing in response to an instrument inserted into the working channel

However, Yoon teaches the valve assembly to be made of a complaint material (col.6, lines 3-5) such as gel material (col.6, lines 11-15) that is susceptible to tearing (col.6, lines 5-10). Therefore, it would have been obvious to a person or ordinary skill in the art, at the time of the invention to modify the valve assembly disclosed by Gentelia

to include rollers made of gel as taught by Yoon. Such a modification would allow more flexibility and range on instruments that can be used with the sealing apparatus.

Claims 47, 48, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentelia et al. (5201714) in view of Gentelia et al. (5599348) and further in view of Yoon (US-5429609).

Gentelia ('714) discloses a trocar assembly, comprising: a cannula (3) having an axis extending between a proximal end and a distal end; a valve housing (2) communicating with the cannula to define a working channel (14); a roller valve (6 or 7) disposed on an axle (10 or 11) in the valve housing, the valve having properties for forming a zero seal across the working channel in the absence of the instrument (fig. 4), and an instrument seal across the working channel in the presence of the instrument (fig.1); wherein the valve comprises: first portions forming a wall seal with the valve housing (wall seal between roller and surface of 13); and second portions forming the zero seal in the absence of the instrument in the working channel (fig. 4), and the instrument seal in the presence of the instrument in the working channel (fig. 1); and Gentelia ('348) discloses the instrument seal having a diameter in radial cross-section ranging from a lower limit of about zero millimeters to an upper limit greater than about 6 millimeters (fig. 6; col.4, lines 24-42).

Gentelia ('714) in view of Gentelia ('348) fail to disclose roller valve including a compliant material, wherein the compliant material includes a gel and includes an inflatable bladder.

However, Yoon teaches a valve assembly having a compliant material, including a gel and an inflatable bladder (36; col.6, lines 11-15). Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention to modify the valve assembly disclosed by Gentelia to include rollers made of gel as taught by Yoon. Such a modification would allow more flexibility and range on instruments that can be used with the sealing apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.Kotini
AU 3731



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

5/29/07